



06-13-01 Submitted by GP/1621
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104 Tasman Court
Cary, NC 27513
10 June 2001 #4

TITLE: Materials and Methods for Measuring Chelate--Anti-chelate Binding by
Fluorescence Polarization Immunoassay

APPLICATION NO.: 09/733,801

FILING DATE: 12/09/2000

FIRST NAMED INVENTOR: David Kenneth Johnson

GROUP ART UNIT: 1621

EXAMINER NAME:

ATTORNEY DOCKET NO.: Johnson 60/17024

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INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents & Trademarks

Washington, DC 20231

Sir:

Applicant submits this Statement in accordance with the duty of disclosure under 37 C.F.R. 1.56 and 1.97-1.98. This statement is filed in accordance with 37 C.F.R. 1.97(b)(3), prior to issuance of a First Office Action on the merits.

U.S. Patent Documents

U.S. Patent No. 6,190,923, JOHNSON David Kenneth, Diethylenetriamine-N,N',N"-triacetic acid derivatives. Issue Date: February 20, 2001. (Referenced in the present application by its application number: 09/148,733.)

U.S. Patent No. 5,631,172, JOHNSON David Kenneth, Metal ion-ligand coordination complexes, antibodies directed thereto, and assays using such antibodies. Issue Date: May 20, 1997.

U.S. Patent No. 4,722,892, MEARES Claude F. and David GS, Monoclonal antibodies against metal chelates. Issue Date: February 2, 1988.

Non-Patent Literature Documents

SUNDBERG MW, Meares CF, Goodwin DA, and Diamanti CI. "Selective binding of metal ions to macromolecules using bifunctional analogs of EDTA." J. Med. Chem. 17 (12), 1304-1307 (1974).

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BRECHBIEL MW, Gansow OA, Atcher RW, Schlom J, Esteban J, Simpson DE, and Colcher D. "Synthesis of 1-(*p*-isothiocyanatobenzyl) derivatives of DTPA and EDTA. Antibody labeling and tumor-imaging studies." *Inorg. Chem.* 25, 2772-2781 (1986).

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GOODWIN DA, Meares CF, McCall MJ, McTigue M, and Chaovapong W. "Pre-targeted immunoscintigraphy of murine tumors with Indium-111-labeled bifunctional haptens." *J. Nucl. Med.* 29, 226-234 (1988).

BLAKE DA, Chakrabarti P, Khosraviani M, Hatcher FM, Westhoff CM, Goebel P, Wylie DE, and Blake RC, II. "Metal binding properties of a monoclonal antibody directed toward metal-chelate complexes." *J. Biol. Chem.* 271(44), 27677-27685 (1996).

KHOSRAVIANI M, Pavlov AR, Flowers GC, and Blake DA. "Detection of heavy metals by immunoassay: optimization and validation of a rapid, portable assay for ionic cadmium." *Environ Sci Technol* 32 (1), 137-142 (1998).

CHAKRABARTI P, Hatcher FM, Blake RC, II; Ladd PA, and Blake DA. "Enzyme immunoassay to determine heavy metals using antibodies to specific metal-EDTA complexes: optimization and validation of an immunoassay for indium." *Analyt. Biochem.* 217, 70-75 (1994).

BRINKLEY M. "A brief survey of methods for preparing protein conjugates with dyes, haptens, and cross-linking reagents." *Bioconjugate Chem* 3, 2-13 (1992).

LE DOUSSAL J-M, Gruaz-Guyon A, Martin M, Gautherot E, Delaage M, and Barbet J. "Targeting of Indium 111-labeled bivalent hapten to human melanoma mediated by bispecific monoclonal antibody conjugates: imaging of tumors hosted by nude mice." *Cancer Res.* 50, 3445-3452 (June 1, 1990).

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DANDLIKER WB, Kelly RJ, Dandliker J, Farquhar J, and Levin J. "Fluorescence polarization immunoassay. Theory and experimental method." *Immunochem.* 10, 219-227 (1973).

OGAN MC, Reiss AC, Croze EM, Jagoda EM, Stouffer BC, Mantha S, Tsay HM, Yost FJ, and Tu J-I. "A specific radioimmunoassay for the measurement of gadoteridol, a contrast agent for magnetic resonance imaging in biological fluids." *J. Pharm. Sci.* 82 (5), 475-479 (May 1993).

REARDAN DT, Meares CF, Goodwin DA, McTigue M, David GS, Stone MR, Jeung JP, Bartholomew RM, and Friucke JM. "Antibodies against metal chelates." *Nature* 316, 265-268 (July 1985).

KHOSRAVIANI M, Blake RC, Pavlov AR, Lorbach SC, Yu H, Delehanty JB, Brechbiel MW, and Blake DA. "Binding properties of a monoclonal antibody directed toward lead-chelate complexes." *Bioconjugate Chem.* 11, 267-277 (2000).

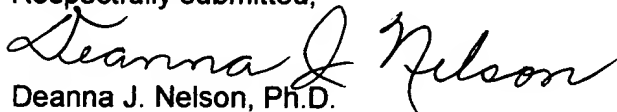
DARWISH IA and Blake DA. "One-step competitive immunoassay for cadmium ions: development and validation for environmental water samples." *Analyt. Chem.* 73 (No. 8), 1889-1895 (April 15, 2001).

ADAMCZYK M, Fishpough JR, Heuser KJ, Ramp JM, Reddy RE and Wong M. "Synthesis of immunocomponents for the measurement of lead (Pb) by fluorescence polarization immunoassay." *Tetrahedron* 54, 3093-3112 (1998).

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A copy of each reference, together with a listing on Form PTO-1449A, is submitted herewith. Applicant respectfully solicits the Examiner's consideration of the cited references and entry thereof into the record of this application.

Respectfully submitted,


Deanna J. Nelson, Ph.D.

Registered U.S. Patent Agent No. 44968

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

Complete if Known

Application Number 09/733,801
 Filing Date 12/09/2000
 First Named Inventor JOHNSON David K.
 Group Art Unit 1621
 Examiner Name
 Attorney Docket Number Johnson 60/17024

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	SUNDBERG MW, Meares CF, Goodwin DA, and Diamanti CI. "Selective binding of metal ions to macromolecules using bifunctional analogs of EDTA." J. Med. Chem. 17 (12), 1304-1307 (1974).	
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Examiner Signature

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Group Art Unit	1621
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